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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,110	09/11/2003	Mark F. Oldham	5010-406	6842

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EXAMINER	
NEGIN, RUSSELL SCOTT	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,110	OLDHAM ET AL.	
	Examiner	Art Unit	
	RUSSELL S. NEGIN	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,23-34 and 36-57* is/are pending in the application.

4a) Of the above claim(s) *57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,23-34 and 36-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Comments

Newly submitted claim 57 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 57 and claims 20, 23-34, and 36-57 are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed serve different functions. While instant claims 20, 23-34, and 36-57 are drawn to a method of improving measurement of one or more types of specific fluorescent particles of a sample by extending the dynamic range of a detector, new claim 57 investigates a different entity of photoelectrons and NOT fluorescent particles. Furthermore, instant claim 57 recites subject matter relating to noise levels and anti-blooming thresholds which, because they are not obvious variants of the invention recited in instant claims 20, 23-34, and 36-57, would require an undue burden to examine. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 57 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 20, 23-34, and 36-57 are pending and claims 20, 23-34, and 36-56 are examined in the instant Office action.

Terminal Disclaimer

The terminal disclaimer filed on 20 February 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 7,423,241 and 6,894,264 has been reviewed and is accepted. The terminal disclaimer has been recorded. The double patenting rejections are withdrawn.

Declaration

The declaration filed on 10 February 2009 under 37 CFR 1.131, in view of amendments filed to the instant set of claims, is sufficient to overcome the Sagatelyan et al. references.

Withdrawn Rejections

The rejections of claims 20, 23-27, 33-34, 36-39, and 45-50 under 35 U.S.C. 102(e) as being anticipated by Sagatelyan et al. are withdrawn in view of amendments filed to the instant set of claims on 10 February 2009.

ALL of the 35 U.S.C. 103 Rejections are withdrawn in view of amendments filed to the instant set of claims on 10 February 2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following rejection is NEWLY applied and necessitated by applicant's amendments:

WRITTEN DESCRIPTION

Claims 20, 23-34, and 36-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended set of claims recites that in each of the two configurations of the photodetector, there is a single set of particles that is out of range of the photodetector. This is new matter.

The instant disclosure illustrates, especially in Figure 13, what applicant possesses with regards to the aspect of the invention relating to extending the dynamic range of the detector. Specifically, in a first configuration of the photodetector, BOTH the first set AND second set of particle are within the dynamic range of the photodetector. In the second configuration of the photodetector, EITHER the first set of

particles is BELOW the threshold limit of the second photodetector OR the second set of particle is GREATER than the threshold limit of the second photodetector. By scaling calculations using the comparative intensities of the two sets of particles WITHIN range in the first photodetector configuration, it is possible to deduce the intensity of the set of particles OUT OF RANGE of the second configuration of the photodetector.

By contrast, the amended set of claims recites that in EACH configuration of the photodetector, ONE of the TWO sets of particles must be out of range of the specific configuration of the photodetector (specifically, if the first set of particles is above the range of the first configuration, the second set of particles is below the range of the second configuration OR if the second set of particles is above the range of the first configuration, the first set of particles is below the range of the second configuration).

Neither Figure 13 of the disclosure, the discussion of Figure 13 in paragraphs [0100] to [0103], or paragraphs [0058] to [0065] of the specification (where applicant points to for support for claim amendments) indicates this scenario. Consequently, applicant lacks support or POSSESSION of the method for extending the dynamic range of the photodetector; the amended limitations constitute NEW MATTER.

The following rejection is NEWLY applied and necessitated by applicant's amendments:

ENABLEMENT

Claims 20, 23-34, and 36-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It would require undue experimentation to scale between two distinct configurations of the photodetector to extend the dynamic range of the photodetector wherein each configuration measures the intensities of the same two sets of fluorescent particles and wherein in each configuration one distinct set of fluorescent particles is out of range of the photodetector.

1. As stated in the written description rejection above, the amended set of claims recites that in EACH configuration of the photodetector, ONE of the TWO sets of particles must be out of range of the specific configuration of the photodetector (specifically, if the first set of particles is above the range of the first configuration, the second set of particles is below the range of the second configuration OR if the second set of particles is above the range of the first configuration, the first set of particles is below the range of the second configuration).

2. As additionally stated in the written description rejection above, the instant disclosure illustrates, especially in Figure 13, what applicant possesses with regards to the aspect of the invention relating to extending the dynamic range of the detector. Specifically, in a first configuration of the photodetector, BOTH the first set AND second set of particle are within the dynamic range of the photodetector. In the second configuration of the photodetector, EITHER the first set of particles is BELOW the threshold limit of the second photodetector OR the second set of particle is GREATER

than the threshold limit of the second photodetector. By scaling calculations using the comparative intensities of the two sets of particles WITHIN range in the first photodetector configuration, it is possible to deduce the intensity of the set of particles OUT OF RANGE of the second configuration of the photodetector. Consequently, the disclosure does not teach how to extend the dynamic range of the photodetector using the scenario recited in the instant claims.

3. The prior art, in the form of Savory et al. [Clinical Chemistry, volume 14, 1968, 132-144] illustrates in Figure 5, two configurations of the gas chromatogram: a first configuration with a maximum peak height of 8 cm and a second configuration with a maximum peak height of 10 cm. All of the six peaks in the configuration with a maximum peak height of 8 cm fall within the range of this chromatogram. However, only two out of the six same peaks fall below the 8 cm threshold when the configuration is changes so that the maximum peak height in 10 cm. Consequently, scaling is possible (using the peak area ratio comparisons described in pages 24-25 of Hanai [HPLC: A Practical Guide, 1999] described in the previous Office action). That is, a fixed ratio needs to be known a given configuration to be applied to a test configuration. As the instant claims recite that there is an unknown intensity that falls out of range at each of the configurations, it is impossible to calculate (and apply) such a ratio (which requires two separately known intensities) when there is only one known peak intensity at each configuration.

4. Consequently, the prior art of Savory et al. and the disclosure demonstrate that for the scaling process to successfully occur in order to extend the dynamic range of a photodetector using two sets of particles in two distinct photodetector configurations, there is a maximum of "one degree of freedom." That is, only one set of fluorescent particles in a single configuration can fall out of range of the photodetector. However, the instant claims recite that each of the TWO sets of fluorescent particles fall out of range of the photodetector- one in the first configuration and the second in the second configuration of the photodetector. The presence of the second degree of freedom in the scaling procedure leads to guessing to determine the fluorescent intensities of the two peaks out of range of the photodetector. This guessing amounts to undue experimentation.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/
Russell S. Negin
30 April 2009

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631